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February 2, 2004

The Honorable Tommy Thompson Secretary Department Of Health and Human Services 200 Independence Ave. S.W. Washington, D.C, 20201

Dear Mr. Secretary;

We write to support the request by Essential Inventions, Inc. that you exercise the provisions of the Bayh-Dole Act with respect to Norvir, a government funded invention by Abbott Laboratories.

Abbott shocked the AIDS affected community and endangered many lives by increasing the price of Norvir by 400% in December 2003. A full treatment of Norvir will now cost over \$46,000, making it by far the most expensive protease inhibitor on the market.

The most common use of Norvir is a booster for other protease inhibitors. For six of the seven non-Abbott protease inhibitors on the market, boosting with Norvir is necessary to achieve maximum medical benefits. Thus, Abbott's price increase has anticompetitively raised the price of its competitor's products.

Abbott did not raise the price of its own Norvir-boosted protease inhibitor, Kaletra. The disparity in the price of Kaletra versus other Norvir boosted protease combinations will negatively impact the health and safety of people with HIV/AIDS in a number of ways. Some insurers may limit people's access to protease inhibitor combinations other than Kaletra and may ban reimbursement for Norvir in its full dose. Many could be left with substandard treatment options, leading to increased risk for illness and even loss of life.

AIDS Drug Assistance Programs, which are already capping enrollment and rationing access to medication because of a lack of needed resources, will see their ranks swell as people are forced our of private sector insurance options and will fell financial strain by commitments to pay private insurance medicine co-payments for many patients. Pharmaceutical assistance programs operated by cities under Title I of the Ryan White Care Act and non-profit treatment clinics around the country are being saddled with the full price increase to the detriment of their ability to serve their patients.

The price increase will also have a negative impact on the development of new protease



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inhibitors that require a boosting dose of Norvir. For example, tipranivir, a new protease inhibitor by Boehringer-Ingelheim, needs to be boosted with 400 milligrams of Norvir. At the new Norvir price, the booster component alone for tipranaivr will cost over \$16,000 a year, destroying the drug's potential to compete with other protease inhibitors for a share of the market for first-line treatments. Therapies that require Norvir boosting may now have to be abandoned due to the astronomical price of Norvir. This threatens salvage patients, the very people who need new anti-HIV drugs the most because they have become resistant or intolerant to all other marketed anti-viral options.

We endorse Essential Inventions' proposed terms for a Bayh-Dole license. First, the license should be open to all qualified applicants so that competitive forces can work to lower prices to consumers to the lowest possible amount, consistent with providing due reward to the patent holder. Second, under the circumstances, we believe that Essential Inventions' proposed royalty term to Abbott of 5% of net generic sales is generous. Third, we endorse the concept of a research and development contribution based on sales of generic Norvir to ensure that use of Bayh-Dole rights does not detract from needed efforts to fund research and development for new HIV/AIDS treatments. We agree with Essential Inventions petition that there may be multiple ways to structure the fund, and to ensure that the fund is transparent and directed toward research and development of new AIDS drugs.

We urge that you act with great haste to alleviate the negative impacts to health and welfare that people with AIDS are facing because of Abbot's unreasonable and abusive pricing of a government funded invention.

Sincerely:

Rhonda Connard

Amanda Lowther

Co-Coordinators
Covenant House AIDS Program

